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APPEAL BRIEF

Applicant	:	George P. Teitelbaum
App. No	:	10/688,135
Filed	:	October 17, 2003
For	:	PERCUTANEOUS VERTEBRAL FUSION SYSTEM
Examiner	:	Jerry L. Cumberledge
Art Unit	:	3733

Mail Stop Appeal Brief-Patents

Commissioner for Patents

P.O. Box 1450

Alexandria, VA 22313-1450

Sir:

In accordance with the Notice of Appeal filed May 7, 2007, Applicant submits this Appeal Brief.

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I. REAL PARTY IN INTEREST

The real party in interest is Medtronic, Inc. of 710 Medtronic Parkway, Minneapolis, Minnesota., which has licensed the patent from the University of Southern California, 3716 South Hope Street, Suite 313, Los Angeles California 9007, which, in turn, owns the patent by virtue of an assignment from the inventor at Reel No. 011395/0750.

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II. RELATED APPEALS AND INTERFERENCES

Appellant is unaware of any related appeals or interferences.

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III. STATUS OF CLAIMS

Claims 1-10 and 13-35 have been canceled. Claims 11, 12 and 36-53 have been finally rejected in the Final Office Action dated February 7, 2007. Claims 11, 12 and 36-53 are being appealed.

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IV. STATUS OF AMENDMENTS

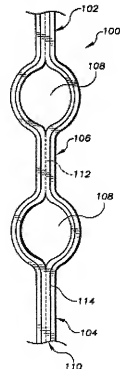
An Amendment After Final was filed under 37 C.F.R. § 1.116 on April 9, 2007. The Examiner has recommended entry of Appellant's Amendment After Final.

V. SUMMARY OF CLAIMED SUBJECT MATTER

Claim 11

11. A directing sheath comprising:
a proximal portion with a proximal end;
a distal portion with a distal end;
a central portion between the proximal portion and the distal portion comprising at least two openings that extend generally traverse to a longitudinal axis of the directing sheath; and
a lumen extending through the directing sheath from the proximal end to distal end generally along the longitudinal axis of the directing sheath and intersecting the at least two openings;
where the directing sheath is scored along its longitudinal axis to allow the directing sheath to be split into two separate halves and dividing the lumen by peeling the directing sheath apart at either its proximal end or its distal end or both along the scoring.

Claim 11 recites a directing sheath 100 comprising a proximal portion 102, a distal portion 104, a central portion 106 comprising at least two openings 108 and a lumen 110 extending therethrough. The directing sheath 100 is scored 112 along its longitudinal axis to allow the directing sheath 100 to be split into two separate halves by peeling the directing sheath 100 apart. Specification, page 11 lines 5-22; Fig. 9.



Claim 44

44. A directing sheath comprising:

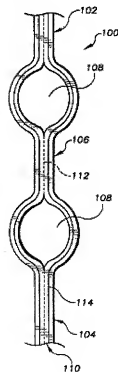
a body extending along an longitudinal axis, the body having a proximal portion with a proximal end; a distal portion with a distal end, and a central portion between the proximal portion and the distal portion;

a longitudinal lumen extending through the directing sheath from the proximal end to distal end generally;

at least two openings that extend through the central portion generally transverse to a longitudinal axis of the directing sheath and intersect the longitudinal lumen; and

where the directing sheath is scored along its longitudinal axis to allow the directing sheath to be split into two separate parts and dividing the longitudinal lumen by peeling the directing sheath apart at either its proximal end or its distal end or both along the scoring.

Claim 44 recites a directing sheath 100 comprising a body having a proximal portion 102, a distal portion 104, a central portion 106 and a lumen 110 extending therethrough. At least two openings 108 extend through the central portion 106. The directing sheath 100 is scored 112 along its longitudinal axis to allow the directing sheath 100 to be split into two separate parts by peeling the directing sheath 100 apart. Specification, page 11 lines 5-22; Fig. 9.



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VI. GROUNDS OF REJECTION TO BE REVIEWED ON APPEAL

- A. The rejection of Claims 11, 36-41, 43, 44, 46-51 and 53 under 35 U.S.C. § 102(e) as being anticipated by Davey (U.S. Publication No. 2005/0027257 A1).
- B. The rejection of Claims 12, 42, 45 and 52 under 35 U.S.C. § 103(a) as being unpatentable over Davey (U.S. Publication No. 2005/0027257 A1) in view of Nissenbaum et al. (U.S. Patent No. 3,155,091).

VII. ARGUMENT

A. The rejection of Claims 11, 36-41, 43, 44, 46-51 and 53 under 35 U.S.C. § 102(e) as being anticipated by Davey (U.S. Publication No. 2005/0027257 A1).

Independent Claim 11 recites, in part, a directing sheath comprising a proximal portion, a distal portion and “a central portion between the proximal portion and the distal portion comprising at least two openings that extend generally traverse to a longitudinal axis of the directing sheath.” Similarly, independent Claim 44 recites, in part, a directing sheath comprising a body having a central portion with “at least two openings that extend through the central portion generally transverse to a longitudinal axis of the directing sheath and intersect the longitudinal lumen.” Claims 11 and 44 were rejected under 35 U.S.C. § 102(e) as being anticipated by Davey.

Davey discloses an introducer sheath 10 that includes “a body portion 12 and a proximal hub portion 14, with a passageway extending through the entire length of the sheath 10.” Davey, Specification [0042] and [0045]; Fig. 13. As illustrated in Fig. 13 reproduced below, the sheath 10 only has an opening at the distal end of the sheath 10 and an opening at the proximal end of the sheath 10 that provide access to the passageway extending through the sheath 10. The central portion of the sheath 10 has no openings whatsoever.

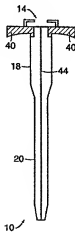
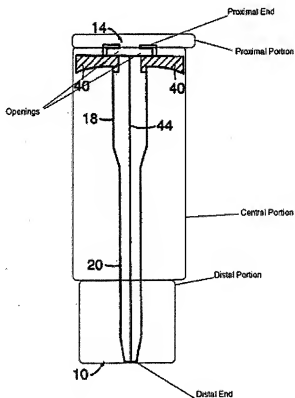


FIG. 13

Nevertheless, the Examiner states that Fig. 13 shows a directing sheath comprising “a central potion (Fig. 13 below) between the proximal portion and the distal portion comprising at least two openings (Fig. 13 below) that extend generally tra[ns]verse to a longitudinal axis of the directing sheath...” Final Office Action, page 3 (referencing a marked up version of Fig. 13 on page 7 of the Final Office Action, reproduced below).



As is clearly evident from the marked up version of Fig. 13, the Examiner has misinterpreted Fig. 13 in several respects. For example, the Examiner circled the topmost portion of the hub 14 and cited it as the proximal portion of the sheath 10. The central portion of the sheath 10, as marked by the Examiner, is shown encompassing both the hub 13 and a portion of the sheath 10. The “openings” referred to in the marked up version of Fig. 13 actually point to a single irregularly shaped opening in the hub that is commonly found in the hub portion of peelable introducers.

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Therefore, Applicant respectfully submits that the Examiner has misinterpreted Fig. 13 of Davey and that a proper interpretation of Davey establishes that Davey does not teach, *inter alia*, “a central portion between the proximal portion and the distal portion comprising at least two openings that extend generally traverse to a longitudinal axis of the directing sheath” or a central portion with “at least two openings that extend through the central portion generally transverse to a longitudinal axis of the directing sheath and intersect the longitudinal lumen.” Thus, Davey does not teach each and every limitation of Claims 11 and 44, and for at least this reason, Applicant submits that Claims 11 and 44 are in condition for allowance.

Claims 36-41 and 43 depend from Claim 11 and Claims 46-51 and 53 depend from Claim 44. Therefore, Claims 36-41, 43, 46-51 and 53 are patentable for at least the reasons set forth above for Claims 11 and 44. In addition, Claims 36-41, 43, 46-51 and 53 are further patentable for the additional features recited therein. For at least these reasons, Applicant submits that Claims 36-41, 43, 46-51 and 53 are in condition for allowance.

B. The rejection of Claims 12, 42, 45 and 52 under 35 U.S.C. § 103(a) as being unpatentable over Davey (U.S. Publication No. 2005/0027257 A1) in view of Nissenbaum et al. (U.S. Patent No. 3,155,091).

Claims 12 and 42, which depend from Claim 11, and Claims 45 and 52, which depend from Claim 44, recite additional features not taught by Davey. Moreover, the combination of Davey and Nissenbaum, which discloses a diagnostic device comprising a tube that is covered with an absorbent sheath made of a woven or knitted fabric, does not cure the deficiencies of Davey, as discussed above for Claims 11 and 44. For at least these reasons, Applicant submits that Claims 12, 42, 45 and 52 are in condition for allowance.

VIII. CLAIMS APPENDIX

Inserted below as a Claims Appendix is a copy of the finally rejected claims in the present case from the Amendment After Final.

1-10. **(Canceled)**

11. A directing sheath comprising:

a proximal portion with a proximal end;

a distal portion with a distal end;

a central portion between the proximal portion and the distal portion comprising at least two openings that extend generally traverse to a longitudinal axis of the directing sheath; and

a lumen extending through the directing sheath from the proximal end to distal end generally along the longitudinal axis of the directing sheath and intersecting the at least two openings;

where the directing sheath is scored along its longitudinal axis to allow the directing sheath to be split into two separate halves and dividing the lumen by peeling the directing sheath apart at either its proximal end or its distal end or both along the scoring.

12. The directing sheath of Claim 11, further comprising a radiopaque filament running the longitudinal length of the directing sheath from the proximal end to the distal end and passing around each opening in the central portion.

13-35. **(Canceled)**

36. The directing sheath of Claim 11, wherein the lumen is configured to receive a guidewire.

37. The directing sheath of Claim 11, wherein the directing sheath is scored completely through a sheath wall of the directing sheath.

38. The directing sheath of Claim 11, wherein the directing sheath is scored completely through a sheath wall of the directing sheath along two opposing lines.

39. The directing sheath of Claim 11, wherein the directing sheath is scored partially through a sheath wall of the directing sheath.

40. The directing sheath of Claim 11, wherein the directing sheath is scored partially through a sheath wall of the directing sheath along two opposing lines.

41. The directing sheath of Claim 11, wherein the directing sheath comprises a biocompatible polymer.

42. The directing sheath of Claim 11, further comprising a radiopaque filament that passes around each opening in the central portion.

43. The directing sheath of Claim 11, wherein the at least two openings are sized substantially the same as a portal on a bone screw.

44. A directing sheath comprising:

a body extending along an longitudinal axis, the body having a proximal portion with a proximal end; a distal portion with a distal end, and a central portion between the proximal portion and the distal portion;

a longitudinal lumen extending through the directing sheath from the proximal end to distal end generally;

at least two openings that extend through the central portion generally transverse to a longitudinal axis of the directing sheath and intersect the longitudinal lumen; and

where the directing sheath is scored along its longitudinal axis to allow the directing sheath to be split into two separate parts and dividing the longitudinal lumen by peeling the directing sheath apart at either its proximal end or its distal end or both along the scoring.

45. The directing sheath of Claim 44, further comprising a radiopaque filament running the longitudinal length of the directing sheath from the proximal end to the distal end and passing around each opening in the central portion.

46. The directing sheath of Claim 44, wherein the lumen is configured to receive a guidewire.

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47. The directing sheath of Claim 44, wherein the directing sheath is scored completely through a sheath wall of the directing sheath.

48. The directing sheath of Claim 44, wherein the directing sheath is scored completely through a sheath wall of the directing sheath along two opposing lines.

49. The directing sheath of Claim 44, wherein the directing sheath is scored partially through a sheath wall of the directing sheath.

50. The directing sheath of Claim 44, wherein the directing sheath is scored partially through a sheath wall of the directing sheath along two opposing lines.

51. The directing sheath of Claim 44, wherein the directing sheath comprises a biocompatible polymer.

52. The directing sheath of Claim 44, further comprising a radiopaque filament that passes around each opening in the central portion.

53. The directing sheath of Claim 44, wherein the at least two openings are sized substantially the same as a portal on a bone screw.

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IX. EVIDENCE APPENDIX

Appellant is submitting no evidence with this appeal.

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X. RELATED PROCEEDINGS APPENDIX

Appellant is unaware of any related appeals or interferences.



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PAT-ABRIEF

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